No. 20-71433

In the United States Court of Appeals for the Ninth Circuit

SUZANNE SISLEY, M.D.; SCOTTSDALE RESEARCH INSTITUTE, LLC; BATTLEFIELD FOUNDATION, DBA FIELD TO HEALED; LORENZO SULLIVAN; KENDRICK SPEAGLE; GARY HESS,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; WILLIAM BARR, ATTORNEY GENERAL; TIMOTHY SHEA, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,

Respondents

PETITIONERS' REPLY BRIEF

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INTRODUCTION

Lacking a meaningful response on the merits, Respondents renew their jurisdictional attack. Those arguments all rest on the same mistaken assumption: that Petitioners cannot obtain judicial review of DEA's final decision denying another's petition for rulemaking under 21 U.S.C. § 811(a).

This case's troubling facts refute Respondents' depiction of Petitioners' injuries as "generalized grievances." DEA's unlawful actions have, for example, impeded Petitioners Sisley and SRI's efforts to conduct clinical research with dispensary-quality marijuana—the very research that DEA has long-insisted must be done before it will reconsider marijuana's Schedule I classification. The Controlled Substances Act ("CSA") provides that "any person aggrieved" may seek judicial review of a final DEA decision. Accordingly, Petitioners' challenge to DEA's 2020 Denial, 1.ER.2, is properly before this Court.

For the reasons stated in Petitioners' opening brief, most of which remain unrebutted, this Court should grant the Petition for Review.

ARGUMENT

I. The Petition Is Properly Before This Court.

A. Petitioners have standing.

1. Article III standing

Respondents' depiction of Petitioners' injuries as "generally available grievance[s] about government," Resp. 15-20, cannot survive confrontation with the facts, *see, e.g.*, Br. 35-43.

1. In brief, Dr. Sisley is an Arizona-based physician. A pioneer in the field of medical-marijuana science, Sisley is DEA-licensed to conduct clinical research with marijuana. For seven years, she did everything by the book. Because marijuana is a Schedule I drug, however, Sisley and SRI must study federal-government marijuana that is unlike dispensary marijuana sold nationwide and inadequate for clinical research. *See* Br. 34-43; 6.ER.1408-18; 5.ER.1015-16.

The veteran-Petitioners served this country and are entitled to medical care from the Department of Veterans Affairs ("VA"). But because marijuana is a Schedule I drug, they must seek—and pay out-of-pocket for—medical advice outside the VA system. 6.ER.1419-24. And as Amicus IAVA explains, the VA refuses to conduct its own research on the marijuana veterans nationwide are using because of marijuana's misclassification. Dkt. 23, IAVA Br. 24.

2. Caught in a "regulatory crossfire," Sisley and SRI have incurred significant expenses that confer constitutional standing. *See, e.g., Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 70 F.3d 1345, 1349 (D.C. Cir. 1995) (association members caught in "regulatory crossfire" had standing to challenge denial of rulemaking petition). Marijuana's misclassification has caused a four-year (and counting) delay in processing SRI's application to cultivate marijuana, prevented SRI from recruiting veterans for clinical trials, and forces it to employ special security measures. Br. 40-43; Dkt. 30, Scientists' Br. 9-12 (explaining special requirements); *e.g.*, 21 C.F.R. §§ 1301.18, 1301.32.

An undisclosed OLC Opinion secretly blocked SRI's application, forced it to sue, and prompted DEA to adopt new rules for registering marijuana manufacturers. Br. 40-43 (citing 2.ER.368, 85 Fed. Reg. 16,292 (Mar. 23, 2020); SER.1-2 & n.5, 85 Fed. Reg. 82,333, 82,334 & n.5 (Dec. 18, 2020) (final rule discussing OLC Opinion)). The new framework is unworkable. Among other things, it requires DEA to take possession of all domestically grown marijuana before it can be used for research or in medicine. The additional costs SRI will incur to comply with this new framework are directly traceable to marijuana's misclassification. 85 Fed. Reg. at 16,293 ("*Because marihuana is a schedule I controlled substance*, applications by

persons seeking to become registered to manufacture marihuana are governed by 21 U.S.C. § 823(a).") (emphasis added); SER.2, 85 Fed. Reg. at 82,334 (similar).

The limitations the CSA imposes "on the number of registrations that DEA may issue to bulk manufacturers of ... schedule I or II controlled substance[s]" do not apply to substances in Schedules III-V. 85 Fed. Reg. at 16,299 (discussing 21 U.S.C. §§ 823(a) and 823(d)). DEA's unlawful misclassification of marijuana thus causes SRI to face steeper competition to obtain a manufacturers' license—another injury-in-fact. *Planned Parenthood v. HHS*, 946 F.3d 1100, 1108 (9th Cir. 2020) (citing cases).

Marijuana's misclassification also forces Sisley and SRI to divert resources away from research[1] and interferes with Sisley's medical practice by depriving her of access to the full spectrum of therapies available under Arizona law when treating PTSD and chronic pain among veterans and law-enforcement officers. 6.ER.1409-10.

1 *See* Br. 40-43 & n.5 (citing 5.ER.1256); *Smith v. Pac. Props. and Dev. Corp.*, 358 F.3d 1097, 1105 (9th Cir. 2004) (diverting resources to "monitor the violations and educate the public" conferred standing); 5.ER.1019 ("Frustrated, Sisley ... went on 'a nationwide tour' ... to talk about the government's stonewalling of cannabis research."); 6.ER.1417-18.

Less profound and particularized injuries have conferred standing. *See, e.g.*, *Flyers Rights Educ. Fund, Inc. v. U.S. Dep't of Transp.*, 810 F. App'x 1, 2 (D.C. Cir. 2020) (association president had constitutional standing to challenge denial of rulemaking petition relating to change fees where "unavoidable change fees make [him] hesitant" to change international flights necessary for job).

2. The D.C. Circuit has twice discussed Article III standing to challenge a § 811(a) petition denial. In *Gettman v. DEA*, 290 F.3d 430, 434 (D.C. Cir. 2002), the court concluded that a former NORML director and High Times Magazine contributor who asserted mere interest in a problem lacked standing. In *Americans for Safe Access v. DEA*, 706 F.3d 438, 445 (D.C. Cir. 2013) ("*ASA*"), by contrast, the court affirmed a veteran's Article III standing because he was "harmed by the DEA's continued classification of marijuana as a Schedule I drug because it deprives him of services that he is entitled to receive free of charge from the VA." That injury was traceable to DEA's decision to deny rescheduling because the VA heeds DEA's judgment regarding marijuana.

Sisley and SRI have stronger claims to Article III standing than petitioners in these cases. DEA's unlawful actions, including refusing to

reconsider marijuana's ongoing misclassification and the 2020 Denial based on the agency's unlawful five-part test, stymie their research.

The same reasons that supported the veteran-petitioner's standing in *ASA* support the veteran-Petitioners' standing here. VA policy still prohibits the VA from facilitating veteran participation in State-approved marijuana programs due to marijuana's Schedule I status. *See* SER.26, VHA Directive 1315 at 1 (Dec. 8, 2017).

3. A ruling for Petitioners would redress these injuries. Redressability amounts to "a significant increase in the likelihood that [Petitioners] would obtain relief that directly redresses the injury suffered." *Utah v. Evans*, 536 U.S. 452, 464 (2002). In addition, "those adversely affected by a discretionary agency decision generally have standing to complain that the agency based its decision upon an improper legal ground." *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 25 (1998). That is true "even though the agency ... might later, in the exercise of its lawful discretion, reach the same result for a different reason." *Id.*

A favorable judicial decision would, at minimum, significantly increase the likelihood that DEA would reschedule marijuana, relieving Petitioners' injuries described above. Similarly, Petitioners contend that DEA based its denial on improper legal grounds. *Id.*

4. Respondents' contrary argument rests on a mistaken premise: that only those who submit petitions to agencies can suffer an Article III injury from a subsequent denial. Consider *Clarke v. Securities Industry Association*, 479 U.S. 388, 392 (1987), where a trade association had standing to challenge a Comptroller decision despite not being the subject of the denied application because the decision implicated an interpretation of a statute that impacted its members. Or take *Massachusetts v. EPA*, 549 U.S. 497, 521 (2007), where Massachusetts had standing to challenge EPA's failure to regulate greenhouse gas emissions even though it had not petitioned EPA to institute rulemaking.

Perhaps because standing in this context is uncontroversial, cases squarely addressing Respondents' argument under the CSA are rare. Petitioners are, however, aware of one—and it undercuts Respondents' position. *See United States v. Creswell*, 515 F. Supp. 1268, 1270 (E.D.N.Y. 1981) ("little question" defendant had standing to challenge DEA's "fail[ure] to grant NORML's [rescheduling petition] since he [wa]s a person adversely affected or aggrieved by agency action") (quotation omitted). In fact, contrary to Respondents' argument, petitioning DEA to institute rulemaking to reschedule a drug does *not* confer Article III standing to challenge a subsequent denial. *See Gettman*, 290 F.3d at 434.

Lacking authority for their lynchpin premise, Respondents resort to inapposite cases. In *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 573 (1992), Resp. 17-18, the Court denied an organization's standing to challenge a rule under the Endangered Species Act where the alleged injury was a member's vague intent to revisit project sites at some indefinite point in the future, at which time he would presumably be denied the opportunity to observe endangered animals. *Lance v. Coffman*, 549 U.S. 437 (2007), Resp. 18-19, is a taxpayer-standing case where plaintiffs asserted standing *as voters* to pursue an Elections Clause claim. In *Smelt v. County of Orange*, 447 F.3d 673, 684 (9th Cir. 2006), Resp. 19-20, plaintiffs lacked standing to challenge the Defense of Marriage Act because they had not "applied for any federal benefits, much less been denied any." But as to Sisley and SRI—who have been systematically impeded by increasingly complex agency machinations, which all rest on DEA's unlawful interpretation of § 812(b)(1)(B) and the unconstitutional § 811(d)(1)—*United States v. Windsor* is more apposite. 570 U.S. 744, 752 (2013). There, Edie Windsor successfully obtained judicial review of an unconstitutional law underlying her injury after the government denied her a tax exemption by not recognizing her same-sex marriage. *Id.*

At bottom, without acknowledging the facts, Respondents portray Sisley as a "plaintiff who complains of gerrymandering, but who does not live

in a gerrymandered district." Resp. 19 (quoting *Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018)). In truth, if the "gerrymandered district" under Respondents' analogy is home to those concretely injured by DEA's unlawful 2020 Denial and marijuana's misclassification, Sisley and SRI don't just live in the district, they're its most prominent residents.

2. Prudential standing

Federal courts have a "virtually unflagging obligation" to adjudicate matters that come within their jurisdiction if Article III standing is present. *Mata v. Lynch*, 576 U.S. 143, 150 (2015) (quotation omitted).

1. Prudential standing turns on whether Petitioners are "person[s] aggrieved" by DEA's 2020 Denial. 21 U.S.C. § 877. If Petitioners "arguably [fall] within the [CSA's] zone-of-interests," *Bonds v. Tandy*, 457 F.3d 409, 411 (5th Cir. 2006), they are "person[s] aggrieved," and this Court has jurisdiction. *See also PDK Labs. Inc. v. DEA*, 362 F.3d 786, 793 (D.C. Cir. 2004); *Clarke*, 479 U.S. at 396 ("person aggrieved" under APA means arguably within the statute's zone-of-interests); Dkt. 14 at 11-13.

This test is lenient in APA cases, where there is a "presumption in favor of judicial review of agency action." *Clarke*, 479 U.S. at 399. "[T]here need be no indication of congressional purpose to benefit the would-be plaintiff." *Id.* at 399-400 (citation omitted). Rather, suit is foreclosed "only when a

plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 225 (2012) (quotations omitted). "Arguably" within the zone-of-interests means "the benefit of any doubt goes" to Petitioners. *Id.*

If Petitioners' interests fall within the underlying statute's "general policy" such that interpretations of its provisions could directly affect them, they fall within the zone-of-interests. *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 500 (1998). This Court is not limited to the statutory provisions Petitioners challenge but may consider any provision that illuminates the statute's purposes. *Clarke*, 479 U.S. at 401.

Petitioners at least arguably lie within the zone-of-interests. In enacting the CSA, Congress sought to ensure that research restrictions, controls on manufacturing, and prescription provisions were commensurate with schedule placements. *See* Br. 18-26 (background and purposes of Act); *e.g.*, 21 U.S.C. § 823 (registration requirements); *id.* § 826 (production quotas). Congress calibrated research and manufacturing controls to the schedules. *See* Br. 20-22. The Act's provisions—particularly its scheduling

provisions like § 812(b)(1)(B)—seek to prevent interference with legitimate medical practice. *See Gonzales v. Oregon*, 546 U.S. 243, 257 (2006).

Licensed researchers and prospective manufacturers subject to DEA regulation like Sisley and SRI have vested interests in ensuring the substances they study are scheduled properly. DEA's own regulations, which define "interested person" as "any person adversely affected or aggrieved by any rule or proposed rule," bear this out. 21 C.F.R. § 1300.01(b). Any person adversely affected by DEA's refusal to initiate proceedings under these provisions is therefore arguably within the statute's zone-of-interests.

Physicians like Sisley have an interest in drugs with a useful and legitimate medical purpose under state law being available for their patients. *See* Dkt. 29, Rice Univ. Br. 13-18 (potential use for chronic pain and to reduce opioid use).

The veteran-Petitioners, afflicted with conditions that make them eligible for medical marijuana under state law, also fall within the zone-of-interests. But-for marijuana's misclassification, they could obtain medical marijuana under "a valid prescription or order," 21 U.S.C. § 844, and receive VA care to which they are entitled.

2. Rather than apply the zone-of-interests test, Respondents rewrite the jurisdictional statute. They replace "any person aggrieved" with

"any party aggrieved" thus denying judicial review to persons who, though not part of the administrative process, are nonetheless aggrieved by its outcome. *See* Dkt. 14 at 12. In *Pacific Maritime Association v. NLRB*, 827 F.3d 1203, 1211 (9th Cir. 2016), however, this Court explained the difference, noting that the "person aggrieved" standard in § 10(f) of the National Labor Relations Act ("NLRA") permitted a non-party to seek judicial review of a final NLRB order.

Respondents note that the trade association in *Pacific Maritime* had attempted to intervene in the administrative proceedings, but they misleadingly suggest that both "the NLRB's denial of intervention *and* NLRB's order regarding a labor dispute that directly affected the employment contract for one of plaintiff's member businesses" meant the association could seek judicial review. Resp. 27 (emphasis added). In fact, the attempted intervention was of no moment: "[E]ven without intervention," plaintiff could obtain judicial review of a final NLRB order in the underlying administrative proceedings because she was a "person aggrieved" (as opposed to "party aggrieved") under the NLRA's judicial-review provision, which is identical in all relevant respects to the one at issue here. *Pac. Mar. Ass'n*, 827 F.3d at 1211 (citing 29 U.S.C. § 160(f)). "[P]arty status [was] not necessary" because "[t]he Act nowhere *requires* an

aggrieved person to have been a party to the underlying proceeding." *Pac. Mar. Ass'n*, 827 F.3d at 1211, 1212. So too here.

Pacific Maritime is no outlier in appreciating the textual distinction between "party aggrieved" and "person aggrieved." In *Simmons v. ICC*, 716 F.2d 40, 43 (D.C. Cir. 1983), then-Judge Scalia, writing for the court, noted that the phrase "party aggrieved" required participation at the agency level and rejected petitioner's argument equating "party aggrieved" with "person aggrieved." *Accord Sierra Club v. U.S. Nuclear Regulatory Comm'n*, 825 F.2d 1356, 1360 (9th Cir. 1987). By implication, the phrase "person aggrieved" must *not* require participation at the administrative level. Likewise, in *In re MG Refining & Marketing, Inc. Litigation*, 1997 WL 23177, at *4 (S.D.N.Y. Jan. 22, 1997), then-Judge Sotomayor explained that "[i]n contrast to the CEA appeal provision addressed to aggrieved '*parties*,' the APA secures judicial review on behalf of any '*person* aggrieved' by an agency decision." Thus, customers who were not parties at the agency got judicial review under the APA's "person aggrieved" standard—the one at issue here. *Id. Compare* 5 U.S.C. § 702 *with* 21 U.S.C. § 877.

B. Exhaustion does not apply.

1. *Darby* forecloses remedies exhaustion

Darby v. Cisneros, 509 U.S. 137, 146-47 (1993), and § 877's "person aggrieved" standard foreclose Respondents' exhaustion argument. *See* Dkt. 14 at 7.

Darby held that § 704 of the APA bars federal courts in APA cases from imposing exhaustion requirements not "clearly mandate[d] ... by the statute or agency rules." 509 U.S. at 146-47. In this APA case, Respondents' failure to identify any CSA provision or DEA rule "clearly mandating" the exhaustion requirement they champion (none exists) is fatal to their exhaustion argument. *See also Young v. Reno*, 114 F.3d 879, 882 (9th Cir. 1997) (*Darby* "limits the discretion of courts to impose exhaustion requirements" beyond statute or agency rules).

Respondents insist *Darby* "only underscores the absence of any authority" for Petitioners' position. Resp. 26. In reciting *Darby*'s holding, however, Respondents confirm its applicability. Resp. 26-27 (parties did not "need to seek further administrative review ... because they were not required to do so by statute or regulation, and because they were challenging final agency action under the [APA]"). Petitioners challenge final agency action reviewable under § 877 and the APA. Nothing in *Darby* or APA § 704 supports Respondents' position, Resp. 27, that participation in underlying

administrative proceedings is a prerequisite to the APA's bar on non-statutory exhaustion of final agency action.

That Petitioners *could* initiate separate administrative proceedings by submitting a different petition is irrelevant. That might give rise to a separate, future right of action. *See Herr v. U.S. Forest Serv.*, 803 F.3d 809, 820 (6th Cir. 2015). But exhausting administrative remedies on a hypothetical petition is irrelevant to Respondents' contention that remedies exhaustion remains possible as to the 2020 Petition (1.ER.1). *See Herr*, 803 F.3d at 820. Respondents identify no additional avenue for administrative relief on the 2020 Petition. Consistent with exhaustion's purposes, remedies exhaustion is something that *must be done* to preserve agency authority, not something *every litigant* must do. Exhaustion is not standing.

The cases Respondents discuss on pages 23-24 of their brief (*Agua Caliente*, *Cabaccang*, and *Paul G.*) are inapposite for reasons detailed in Petitioners' prior briefing. Dkt. 14 at 8-10 (discussing those cases). They do not involve final agency action subject to judicial review by statute.

Washington v. Barr, 925 F.3d 109, 115-18 (2d Cir. 2019), a case Respondents still insist presents "similar circumstances," Resp. 24, didn't involve the APA at all. There, plaintiffs raised constitutional claims in district court—different from the posture here—so *Darby* and the APA did not apply.

2. Even without *Darby*, exhaustion is excused

Courts require remedies exhaustion to protect agency authority and promote judicial efficiency. *McCarthy v. Madigan*, 503 U.S. 140, 145 (1992). Petitioners previously argued that exhaustion should not apply because DEA lacks expertise on the pure legal issues before the Court and further delay would unduly prejudice Petitioners. Dkt. 14 at 18-20.

Respondents do not deny that "the average delay in deciding petitions to reclassify drugs under the CSA is approximately *nine years*." *Washington*, 925 F.3d at 120 (emphasis added). And while they find Petitioners' argument that DEA lacks expertise in construing § 812(b)(1)(B) "difficult to fathom" today, DEA had no such difficulty in 1992 when it promulgated the authoritative statement of the five-part test's rationale. *See* Br. 68. Nor did the Supreme Court in *Oregon*. 546 U.S. at 268-69. Nor did *this Court* in *Oregon v. Ashcroft*, 368 F.3d 1118, 1130 (9th Cir. 2004).

Elgin v. U.S. Department of Treasury, 567 U.S. 1 (2012) does not hold that every facial constitutional challenge must be exhausted. There, as Respondents acknowledge, the agency could have applied its expertise by deciding in the employees' favor on other grounds. Resp. 26 (citing *Elgin*, 567 U.S. at 141-42). Here, by contrast, because the Single Convention covers marijuana, § 811(d)(1) applies, making avoidance impossible.

Petitioners previously noted futility. Dkt. 14 at 16 n.3. That point now merits elaboration. In *Washington*, it was "conceivable that, in response to a petition from Plaintiffs along the lines advanced before us now, the DEA would reschedule marijuana." 925 F.3d at 117. This Court need not entertain that hypothetical here.

In February 2019, Carl Olsen petitioned DEA for an exemption under 21 C.F.R. § 1307.03. *See* SER.29. More than a month *after* Petitioners filed their opening brief refuting DEA's five-part test, DEA denied Olsen's petition, forcefully asserting its five-part test and explaining that § 811(d)(1) and international law require marijuana's placement in Schedules I or II. SER.30-31.

In insisting Petitioners submit a petition before seeking judicial review, Respondents demand a quintessential futile act. Judge Sutton's opinion for the Sixth Circuit in *Herr*, 803 F.3d at 822, is instructive on this point. He described exhaustion as "futile" where the Forest Service previously rejected similar challenges to the same agency action and offered no indication it would have treated Herr's any differently. *Id.* at 823. Just so here.

No interest favors exhaustion. While this action was pending, DEA had an opportunity to correct its mistake. It doubled down. And no larger administrative record or agency expertise is needed to adjudicate the pure

legal questions before this Court. There is every reason to excuse exhaustion, however: an "unreasonable or indefinite timeframe for administrative action," *McCarthy*, 503 U.S. at 147; irreparable injury from delay as DEA moves forward with final rules regarding cultivation applications premised on marijuana's misclassification, *id.*; no institutional competence to resolve the issue of whether a statute is facially invalid under the non-delegation doctrine, *id.*; and DEA has plainly "predetermined the issue[s] before it," *id.* at 148.

3. Issue exhaustion does not apply

Respondents never overtly raise issue exhaustion, but they imply it. *E.g.*, Resp. 23, 28. Previously, Petitioners distinguished remedies and issue exhaustion, Dkt. 14 at 14-15, and yet Respondents, in both their statement of issues and their argument supporting them, present only remedies exhaustion. This issue is therefore waived. *See, e.g.*, *United States v. Kama*, 394 F.3d 1236, 1238 (9th Cir. 2005). Furthermore, the doctrine is inapplicable here anyway.

First, the 2020 Petition raised the issue using the language of the statute: maintaining marijuana in Schedule I is untenable because "[h]alf the states allow for *medical use*." 1.ER.1 (emphasis added). DEA considered and rejected this argument, attaching the 2016 Denial. 1.ER.6.

"[A] claimant need not raise an issue using precise legal formulations, as long as enough clarity is provided that the decision maker understands the issue raised." *Lands Council v. McNair*, 629 F.3d 1070, 1076 (9th Cir. 2010). "[A]lerting the agency in general terms" is enough if the agency has been given "a chance to bring its expertise to bear to resolve [the] claim." *Id.* (citation omitted). For example, in *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 898-99 (9th Cir. 2002), this Court held that plaintiffs' presentation of "a much less refined" legal argument in their administrative appeal was sufficient to exhaust the more detailed argument they raised on judicial review because the administrative decisionmaker "understood plaintiffs to raise the issue" and addressed it.

DEA cannot claim surprise by Petitioners' arguments when the 2020 Denial anticipated and addressed them (unlawfully). Respondents recount the details: the agency invoked the 2016 Denial, the five-part test, and § 811(d). Resp. 5-6, 44 n.10. If the 2020 Petition didn't implicate the propriety of DEA's five-part test, why is it the centerpiece of DEA's letter refusing to initiate proceedings by incorporating the 2016 Denial? The same goes for the § 811(d)(1) issue.

Second, even when a party fails to raise an issue at the administrative level, it is exhausted if the agency considers and decides it. *Abebe v.*

Gonzales, 432 F.3d 1037, 1041 (9th Cir. 2005) (en banc); *W. Radio Servs., Co. v. Qwest Corp.*, 530 F.3d 1186, 1203 (9th Cir. 2008).

Third, unlike *Dombeck*, neither the statute nor the regulations at issue here requires exhaustion, and the § 811(a) petition process is inquisitorial and informal. Under *Sims v. Apfel*, these features render non-statutory issue exhaustion inappropriate. 530 U.S. 103, 107-08 (2000). *See also Alaska Survival v. Surface Transp. Bd.*, 705 F.3d 1073, 1080 (9th Cir. 2013) (no issue exhaustion with "informal" and "inquisitorial rather than adversarial" proceedings); Dkt. 14 at 15-16.

Ignoring *Sims*, Respondents revert to the "exceptional circumstances" test from *Getty Oil Co. v. Andrus*, 607 F.2d 253, 256 (9th Cir. 1979). To the extent *Getty Oil* requires a different result than *Sims*, however, *Sims* controls. Nor does *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952), help Respondents since it involved issue exhaustion in an adversarial proceeding. Furthermore, issue exhaustion would not apply even under that standard for the same reasons remedies exhaustion would be excused if it applied, *see Marathon Oil Co. v. United States*, 807 F.2d 759, 768 (9th Cir. 1986) (describing standard), especially because public health is at stake, *see League of United Latin Am. Citizens v. Wheeler*, 899 F.3d 814, 828 (9th Cir. 2018).

II. The 2020 Denial Rests on an Unlawful Interpretation of § 812(b)(1)(B).

A. Respondents effectively concede that the five-part test violates the CSA's plain language.

Respondents ignore Petitioners' arguments demonstrating that the five-part test violates the CSA's text in numerous ways. Br. 47-66. Respondents do not counter with as much as a dictionary definition in support of their interpretation let alone employ a tool of statutory construction at any point in their brief. Instead, they resort to policy arguments and *Chevron* deference.

As Petitioners explain next, these non-textual arguments are meritless. But because Respondents do not seriously dispute that the five-part test violates § 812(b)(1)'s plain language, this Court need not address them to resolve this case.

B. Respondents' meritless policy arguments do not justify ignoring statutory text.

Respondents' defense of the five-part test rests on two main points—that accepting Petitioners' arguments would force DEA to

1. rubberstamp state acceptance of drugs like heroin or Quaaludes, and remove them from Schedule I despite overwhelming evidence they are dangerous and ineffective, Resp. 33-34, and

2. defer to state acceptance of a drug's medical use because "[s]tate laws concerning marijuana are not required to be premised on

> the same rigorous and extended scrutiny that precedes FDA's approval of a new drug application," Resp. 33.

These arguments underscore Respondents' fundamental misunderstanding of Petitioners' claims, the CSA's scheduling regime, and DEA's role in administering it.

First, Petitioners do not argue that DEA must rubberstamp state acceptance of a drug's medical use regardless of science or evidence. Instead, they argue that DEA may not treat a historic wave of state acceptance of a substance's medical use as categorically irrelevant to the § 812(b)(1)(B) inquiry. While other cases might present line-drawing issues regarding what, exactly, is required to demonstrate currently accepted medical use, this Court need not address those questions here because acceptance by a supermajority of States is indisputably "sufficient [grounds] to justify the initiation of proceedings" under § 811(a). 21 C.F.R. § 1308.43(c).

Nor do Petitioners seek to deprive DEA of access to scientific evidence. Respondents cite nothing in Petitioners' opening brief or the record to support their claim to the contrary, which is remarkable considering that it is, in fact, Respondents who seek to narrow the universe of evidence available in § 811(a) proceedings by treating a historic wave of state acceptance of marijuana's medical use as irrelevant.

Second, Respondents' arguments underscore how far the five-part test strays from the CSA's text. Their parade of horribles assumes that because Schedule I contains very dangerous drugs, Congress could not have intended to permit States to effectively force drugs from Schedule I to Schedule II simply by accepting their use as medicine. As Petitioners' opening brief explained, however, FDA—the agency whose medical and scientific judgments Congress made *binding* on DEA, *see* 21 U.S.C. § 811(b)—agreed with Petitioners, at least in the years closer to the time of the CSA's enactment and before DEA announced its five-part test.[2] Indeed, according to the architect of the schedules, that is precisely what Congress intended with this language: "*If the doctors say there is a use for heroin as a medically prescribed drug, it has to go down to No. 2.*"[3] That Respondents offer neither a response to those authorities nor any statutory defense of their own is telling.

The parade of horribles also reflects Respondents' misunderstanding of the CSA's scheduling regime: they assume that whether a substance

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[2] Br. 49-50 (quoting 2.ER.226-27, 47 Fed. Reg. 28,141 at 28,150-51 (June 29, 1982) and 4.ER.839-40, 12 FDA Drug Bull. 4-5 (Apr. 1982)).

[3] SER.44, *Drug abuse control amendments—1970. Hearings,* 91st Cong., 2d Sess., on H.R. 11701 and H.R. 13743 at 707 (statement of M. Sonnenreich) (emphasis added).

belongs in Schedule I depends on its dangerousness relative to other drugs. Not so. Schedule II includes substances like methamphetamine and cocaine that are more dangerous than some Schedule I drugs. *See* 2.ER.191, 204-05. Yet their Schedule II classification has neither impeded law enforcement nor made them widely available since drugs in Schedules I and II are subject to the same DEA-controlled production quotas. 21 U.S.C. § 826(a)(1). In fact, DEA's quotas for Schedule II drugs are often *lower* than those it sets for Schedule I substances. *E.g.*, 85 Fed. Reg. 54,414, 54,416 (Sept. 1, 2020).

The only *real* difference is that Schedule II drugs are available for medical use while Schedule I drugs are not. *Compare* 21 U.S.C. § 812(b)(1)(B) *with id.* § 812(b)(2)(B). The core question thus becomes

> *Did Congress intend to delegate to DEA the power to declare that a substance a supermajority of the States agree has a currently accepted medical use, in fact, does not?*

Not only does the CSA's plain text command a negative answer, so does *Oregon*, 546 U.S. at 243. There, the States' long-established role as the traditional gatekeepers of the medical practice in our federal system foreclosed the Attorney General's attempt to impose his vision of "legitimate" medical practice on a single State. *A fortiori*, DEA may not impose that same vision on a *supermajority* of States through its five-part test. The only permissible reading of the text is the one that squares with *Oregon*: DEA

cannot make "anterior judgment[s]" about the "understanding of medicine's boundaries" for the second factual finding for Schedules I *or* II. *Id.* at 272.

Notably, Respondents have *never* argued that the phrase "currently accepted medical use" calls for medical judgment any less than the phrase "legitimate medical purpose" that was at issue in *Oregon*. And less than a year after *Oregon*, in the context of opioid prescriptions, DEA acknowledged it lacks authority in any area touching on traditional state regulation of the medical profession:

> DEA does not act as the Federal equivalent of a State medical board overseeing the general practice of medicine. State laws and State licensing bodies ... collectively regulate the practice of medicine. In contrast, the scope of the CSA (and therefore role of DEA) is much narrower.

SER.36, 71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006).

Respondents' remaining arguments are easily dispatched.

C. *Chevron* does not apply.

Respondents cannot explain why *Oregon*'s holding that *Chevron* did not apply to the Attorney General's attempt to impose his vision of the practice of medicine on Oregon does not apply with even greater force to DEA's attempt to impose that same vision on a supermajority of States in this case. 546 U.S. at 245. They emphasize that unlike this case, *Oregon* did not arise in the scheduling context, Resp. 36, but *Oregon* addressed that

distinction and emphasized that applying *Chevron* here would be even *less* appropriate:

> The CSA allocates decisionmaking powers ... *so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary*. *In the scheduling context*, for example, the Secretary's recommendations on scientific and medical matters bind the Attorney General.
>
> ....
>
> The structure of the CSA, then, conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise.

546 U.S. at 266-67 (emphasis added).

Regarding the CSA's status as a dual-application statute, Respondents offer only that "[a]ny concerns about fair notice of what the criminal law requires are absent here, where it is obvious from the Controlled Substances Act that marijuana is a schedule I substance." Resp. 37-38 (citations omitted). But that misses the point. *Guedes v. ATF*, 140 S. Ct. 789, 790 (2020) (statement of Gorsuch, J., respecting denial of certiorari) ("[W]hatever else one thinks about [judicial deference], it has no role to play when liberty is at stake.").

Respondents' attempt to invoke *Chevron* thus rests on a handful of cases applying its framework to DEA interpretations of the CSA in circumstances very different from those presented here. Resp. 33-35

(discussing cases). For three reasons, none changes the analysis: (1) most assumed *Chevron* applied without discussion; (2) none addressed the issues presented here; and (3) *Oregon* controls in any event. Indeed, in *Oregon*, the Court considered and rejected the United States' invocation of *Chevron* based on the D.C. Circuit decision Respondents primarily rely on here. Br. for U.S., *Gonzales v. Oregon*, 2005 WL 1126079, at *21 (U.S. May 12, 2005) (arguing that DEA's interpretation merited deference because "neither the statute nor its legislative history precisely defines the term 'currently accepted medical use'" (quoting *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991) ("*ACT I*")).

D. Even if *Chevron* applied, it could not save the five-part test.

1. Section 812(b)(1)(B) is not genuinely ambiguous.

Respondents insist § 812(b)(1)(B) is ambiguous because the CSA doesn't define "currently accepted medical use." Resp. 34-35. But "[a] statute's terms are not ambiguous simply because the statute itself does not define them." *Medina Tovar v. Zuchowski*, 2020 WL 7064628, at *2-3 (9th Cir. Dec. 3, 2020) (en banc). Because Respondents do not address Petitioners' textual arguments, they have not demonstrated that "Congress's meaning" is not "discern[able]" with the aid of the "traditional tools of statutory construction." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018).

Aside from *ipse dixit*, Respondents' only support for the proposition that § 812(b)(1)(B) is ambiguous is a few out-of-circuit cases. Resp. 34-35 (citing cases). None helps Respondents.

Respondents note that ambiguity was undisputed in *Grinspoon v. DEA*, 828 F.2d 881, 885 (1st Cir. 1987). Resp. 14, 33-34. But (1) ambiguity *is* disputed here, and (2) at least with respect to the precise question at issue, the First Circuit *disagreed* with the parties. *Grinspoon*, 828 F.2d at 885 & n.6 (declaring DEA's interpretation "contrary to congressional intent" and "would be invalid even under the second prong of the *Chevron* test"). *Grinspoon* thus supports *Petitioners*' argument that statutory phrases "may be ambiguous in some respects yet still sufficiently clear to evince Congress's intent on certain other issues." Br. 69 (citing *Cuomo v. Clearing House Ass'n*, 557 U.S. 519, 525 (2009)).

ACT I, 930 F.2d at 939, declared § 812(b)(1)(B) ambiguous simply because "neither the statute nor its legislative history precisely defines the term 'currently accepted medical use,'" a practice that, as mentioned *supra* 36, courts have since rejected. And because the follow-up opinion in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1134 (D.C. Cir. 1994) ("*ACT II*"), simply adopted *ACT I*'s *Chevron* analysis as "law of the case," it also fails to advance the ball for Respondents.

Petitioners in *ASA* did "not seriously dispute the propriety of the five-part test," so the court cited *ACT I* and deferred to DEA without analysis. 706 F.3d at 450. And *Krumm v. DEA*, 739 F. App'x 655 (D.C. Cir. 2018)—a per curiam judgment in a pro se action—is even less relevant since it simply cites *ASA* and rejects petitioner's claims without analysis.

2. Even if § 812(b)(1)(B) were genuinely ambiguous as to this question, DEA's interpretation fails at step two.

Petitioners offered five reasons why DEA's application of the five-part test in the 2020 Denial would fail at *Chevron* step two even if § 812(b)(1)(B) were ambiguous. Br. 69-76. Respondents ignore most of those arguments, including that

(a) DEA relied on factors Congress didn't intend for it to consider and failed to consider an important part of problem, Br. 70-71;

(b) DEA's repeatable-chemistry requirement ignores the CSA's definition of marijuana, Br. 71-73;

(c) DEA's five-part test makes the CSA more effective at preventing research than diversion and abuse, Br. 73-74; and

(d) DEA's five-part test invites absurd results, Br. 66-67, 75-76.

Even if this Court disagrees with Petitioners on other points, it should reject the five-part test for those unrebutted reasons.

Respondents do defend DEA's differential treatment of FDA and state acceptance of drugs arguing "state laws concerning marijuana are not required to be premised on the same rigorous and extended scrutiny that

precedes FDA's approval of a new drug application." Resp. 33. There is no support for that argument in the record, and, in all events, DEA has admitted it lacks authority to judge the relative merit of FDA's and the States' approaches. Br. 68; SER.36, 71 Fed. Reg. at 52,717.

III. Respondents Do Not Address Petitioners' "Insubstantial" Non-Delegation Arguments.

Petitioners raise two important non-delegation arguments.

Petitioners' primary argument regarding the *private* non-delegation doctrine, Br. 77-79, is so "insubstantial" that it is unrebutted. Under this doctrine, delegations of regulatory power to private parties are impermissible, *U.S. Dep't of Transp. v. Ass'n of Am. R.Rs.*, 575 U.S. 43, 87 (2015) (Alito, J., concurring) (citing *Carter v. Carter Coal Co.*, 298 U.S. 238, 311 (1936)), intelligible principle or not. It is different from the more commonly urged non-delegation line, which focuses on whether Congress laid down an intelligible principle for an agency to follow. *See Ass'n of Am. R.Rs.*, 575 U.S. at 87-88.

Respondents argue that Congress provided an "intelligible principle" under § 811(d)(1). This is a red herring. "Even an intelligible principle cannot rescue a statute empowering private parties to wield regulatory authority." *Ass'n of Am. R.Rs. v. U.S. Dep't of Transp.*, 721 F.3d 666, 671 (D.C. Cir. 2013). They cannot dispute the pertinent point: no different than *Carter Coal*,

§ 811(d)(1) impermissibly gives regulatory power to a non-governmental entity (here, the World Health Organization) to dictate criminal law, and the Attorney General must oblige.

Petitioners' second argument is that § 811(d)(1) lacks an intelligible principle because it expressly disclaims any. Br. 79-80. Again, Respondents confuse the legal inquiry. They correctly explain that Congress must "lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform," Resp. 39 (citing *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001)), but they never explain how the *legislative act* provides one. Instead, Respondents emphasize that in exercising the mandate under § 811(d)(1), DEA *applied* the intelligible principle the statute disclaims. Resp. 43-44.

This conflates whether *DEA applied* an intelligible principle with whether *Congress provided one* by statute. No doubt, courts have held that § 812(b) is an intelligible principle. *See* Resp. 41. But the non-delegation problem Petitioners flag is that § 811(d)(1), the statute, does not provide the principle, and even more, it disclaims any. That DEA, with its unfettered discretion, chooses to apply § 812(b) is precisely the problem.

CONCLUSION

DEA's five-part test is a relic of a bygone era of "reflexive" *Chevron* deference. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (quotation omitted). Because "seeming ambiguities" may often be resolved by carefully considering text, structure, history, and purpose, however, courts may no longer "wave the ambiguity flag" just because a statute does not define a key term. *Id.*

DEA's construction of § 812(b)(1), which has not seen rigorous judicial scrutiny since 1987 when the First Circuit in *Grinspoon* held that "no currently accepted medical use" does *not* mean FDA approval (contrary to DEA's position), cannot survive once this Court takes the traditional tools of construction in hand, as *Kisor*, *Iancu*, and *Oregon* demand. With them, the meaning of the text is unambiguous: it bakes Our Federalism into the Act and forecloses DEA's attempt to impose its vision of acceptable medical practice on a supermajority of States.

Tellingly, unable to refute Petitioners' textual arguments, Respondents are left attempting a jurisdictional heist.[4] Dr. Sisley is the one doctor in this

[4] The strategy, as a previously undisclosed 1972 memorandum from the Nixon Archives reveals, is almost as old as the CSA itself. SER.45-46 (explaining that, in response to the 1972 NORML Petition, among other things, DEA's predecessor could not "deceive the courts by using [lack of

country who, for the sake of her veteran- and law-enforcement patients, picked up DEA's gauntlet and threw her entire life behind unearthing the scientific truth about marijuana's medicinal potential only to find herself ensnared in a Catch-22 of the agency's making. Yet, to get this Court to look the other way, Respondents portray her and the other Petitioners as suffering "generalized grievances" unworthy of judicial review. Even more, they urge this Court to defy the text of § 877 and the APA and require that she—a DEA-licensed researcher who did everything by the book and whose application to grow marijuana suitable for clinical research has languished in agency purgatory for over four years—pointlessly submit a different petition and obtain a preordained denial all in the name of non-statutory exhaustion that cannot apply here.

This Court should not abide. Petitioners request that it grant the Petition for Review, set aside DEA's five-part test, declare § 811(d)(1) unconstitutional, and instruct DEA to complete the formal rulemaking process required under § 811(a) within one year of this Court's mandate.[5]

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standing] as a delay tactic knowing that if we lose, we will be back later with our real reason for rejecting the petition"). *See also* Br. 26-27.

[5] Petitioners received Respondents' Rule 28(j) letter hours ago and will respond shortly. In brief, Respondents alert this Court to *Zyszkiewicz v. Barr*, No. 20-5213 (D.C. Cir. Dec. 2, 2020), a per curiam decision affirming dismissal of a pro se mandamus action Zyszkiewicz filed in district court. The D.C. Circuit agreed with the district court that an

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Respectfully submitted,

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STATEMENT OF RELATED CASES

Petitioners are unaware of any related pending appeals within the meaning of Circuit Rule 28-2.6.

"adequate alternative remedy under the Controlled Substances Act" was available to Zyszkiewicz—judicial review under § 877—thus precluding mandamus. The district court had focused on Zyszkiewicz's failure to take advantage of the statutory judicial-review mechanism Petitioners timely engaged here—filing a petition for review "in the United States Court of Appeals ... within thirty days after notice of [DEA's final] decision." *See Zyszkiewicz v. Barr*, 2020 WL 3572908, at *1 (D.D.C. June 30, 2020) (citing 21 U.S.C. § 877). Because Petitioners did just that, *Darby* precludes the possibility of further exhaustion.

CERTIFICATE OF COMPLIANCE

No. 20-71433

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Georgia font and is proportionally spaced. I further certify that this brief complies with the type-volume limitation of Circuit Rule 32-1 because it contains 6,992 words, excluding the items exempted by Federal Rule of Appellate Procedure 32(f), according to Microsoft Word 2016.

Dated: December 21, 2020

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed this document with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on December 21, 2020. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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